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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,664	01/22/2004	David J. Beebe	282.033	5152

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
11/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/762,664	BEEBE ET AL.	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,17,20,21 and 24-28* is/are pending in the application.

4a) Of the above claim(s) *9,17,20 and 25* is/are withdrawn from consideration.

5)☒ Claim(s) *26* is/are allowed.

6)☒ Claim(s) *21,27 and 28* is/are rejected.

7)☒ Claim(s) *24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 9/15/2008.

2. In the reply, the Applicant amended claims 21, 24, 26 and 27 and cancelled claim 23 and placed the subject matter into claim 26.

3. Thus, claims 21, 23-24, 26-28 remain pending.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a conduit having an input communicating with the aqueous solution and an output, the conduit having a first configuration wherein the aqueous solution is isolated from the chamber and a second configuration wherein the chamber communicates with the aqueous solution through the conduit" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21, 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant amended the claims to include:

> *"a conduit having an input communicating with the aqueous solution and an output, the conduit having a first configuration wherein the aqueous solution is isolated from the chamber and a second configuration wherein the chamber communicates with the aqueous solution through the conduit."*

4. The originally filed specification fails to disclose this newly claimed conduit having first/second configurations. The pertinent drawings Figs 1-4 do not show a conduit having first/second configurations. The specification lacks any discussion of a conduit having first or second configurations. The Applicant cited page 8, lns 28+ as

reference to the disclosure. However, the Examiner only found pertinent disclose on pg 9 lns 1-9:

> *"Microfluidic device 10 further defines pressure source cavity 46 that is isolated from reservoir 14 by flexible membrane 48. A plurality of hydrogel pressure sources 50 are spatially disposed within pressure source cavity 46. Hydrogel pressure sources 50 are responsive to a trigger such as a buffer solution injectable into pressure source cavity 46 either during or after fabrication of body 12. In the depicted embodiment, the buffer solution injected into pressure source cavity 46 and body 12 causes hydrogel pressure sources 50 to expand and exert a pressure on flexible membrane 48, for reasons hereinafter described." (emphasis added)*

4. The Examiner finds no disclosure of a conduit as claimed within the Applicant's originally filed disclosure. Further, the Examiner notes that the current claim recitation is very confusing. How can the chamber communicate with the aqueous solution through the conduit? The chamber is not movable. It appears to the Examiner that the aqueous solution would communicate through the conduit into the chamber. Is the conduit an integral part of the body (definitely can interpreted so from the claim language)? The Examiner suggests clarifying language. Lastly, the Examiner suggests using language gleaned from the specification recited above to define/claim the filling procedure. This will alleviate the new matter issues.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 27 recites the limitation "the predetermined physical property" in 7. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Ziaie et al (2004/0248326). Ziaie et al discloses in reference to claim 21 a microfluidic device (Fig 13) for delivering a drug to an individual, comprising: a body (504) defining a reservoir for receiving the drug and a chamber for receiving an aqueous solution therein ([0028] wherein the insulin pump may be an osmotic pump which are well known in the art to have a drug contained in a reservoir formed by a membrane surrounding the drug, a osmotic agent containing chamber between the membrane a semipermeable membrane holding the osmotic agent and the semipermeable membrane being capable of being permeable to an aqueous solution which flows through the semipermeable membrane increasing the volume of the chamber and exerting pressure on the reservoir); an output cannula (502) having an input in communication with the reservoir (Fig 13) and an output receivable within the individual (Fig 13); an adhesive (Fig 13) for affixing the body to the individual; a pressure source (see discussion above) including an hydrogel member received within the chamber (wherein the osmotic agent may be considered a hydrogel [0145]) and being expandable in response to exposure to a the aqueous solution (see discussion above), the hydrogel member engageable with the reservoir and urging the drug from the reservoir through the output cannula as the

hydrogel member expands ([0143-0147]); and a valve (500; Fig 9-10) defining a chamber and interconnecting the reservoir and the output cannula (Fig 13), the valve movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle (Fig 9-10, 13; [0017, 0028, 0143-0147] and discussion of "Hydrogel-Activated Devices").

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 21, 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kriesel et al (6416495) in view of Kriesel et al (5693018). In reference to claim 21 Kriesel et al '495 discloses a microfluidic device (Fig 4) for delivering a drug to an individual, comprising: a body (24) defining a reservoir (44) for receiving the drug and defined by a membrane (50) and a chamber (70) for receiving an aqueous solution therein; an output cannula (137) having an input in communication with the reservoir (Fig 4) and an output receivable within the individual (Fig 3, 4, Summary); a pressure source (70) including an hydrogel member received within the chamber (70) and being expandable in response to exposure to the aqueous solution (col 6, lns 33-47, col 10, lns 9-21; and specifically col 7, lns 1-32 or col 9 lns 56-58; wherein the hydrogel is disclosed as being the type that responds to a ph or salt concentration change that

occurs in an aqueous solution), the hydrogel member engageable with the reservoir and urging the drug from the reservoir through the output cannula as the hydrogel member expands (Fig 4, Summary, col 5, lns 15-col 6, lns 1, col 6, lns 33-47, col 10, lns 9-21); and a valve (64) defining a chamber and interconnecting the reservoir and the output cannula (Fig 4), the valve movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle (64, Fig 4, Summary, col 5, lns 15-col 6, lns 1, col 6, lns 33-47, col 10, lns 9-21).

9. In response to claims 27-28, Kriesel et al '495 discloses the invention substantially as claimed and further discloses that the hydrogel member is expandable in response to exposure to a predetermine physical property originating within the body (col 6, lns 33-47, col 10, lns 9-21; and specifically col 7, lns 1-32 or col 9 lns 56-58; wherein the hydrogel is disclosed as being the type that responds to a ph or salt concentration change that occurs in an aqueous solution; furthermore, see col 11, col 21-25, wherein a sensor is exposed to a predetermined physical property originating within the body in the bloodstream which is an aqueous solution. In this case, the sensor can activating any one of the disclosed (magnetic, light, electrical) methods of activating the hydrogel member in response to an exposure to a predetermine physical property originating within the body.

10. However, Kriesel et al '495 does not expressly disclose that the output cannula is a needle and that the device has an adhesive for affixing the body to the individual.

11. Kriesel et al '018 teaches that it is known to have the output cannula is a needle (26b) and that the device has an adhesive (layer "A") for affixing the body to the individual for the purpose of providing a subdermal insulin delivery device that is attached to the patient's skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the output cannula and device as taught by Kriesel et al '495 with the output needle and adhesive securement as taught by Kriesel et al '018 for the purpose of a subdermal insulin delivery device that is attached to the patient's skin.

12. Claims 21, 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckenhoff et al (4552561) in view of Ziaie et al (20040248326). Eckenhoff et al discloses a microfluidic device (Fig 2) for delivering a drug to an individual, comprising: a body (2) defining a reservoir (25) for receiving the drug and being defined by a membrane (16) and a chamber (11) for receiving an aqueous solution (18) therein; an output cannula (22, 21) having an input in communication with the reservoir (Fig 2) and an output receivable within the individual (Fig 2); a pressure source (18) including an hydrogel member received within the chamber and being expandable in response to exposure to a the aqueous solution (see discussion above), the hydrogel member engageable with the reservoir and urging the drug from the reservoir through the output cannula as the hydrogel member expands ([col 4, lns 15-35; col 5, lns 53-43]); an output needle (22), and an adhesive (6). *The Examiner also references col 6, lns 20-28 where*

it is discussed filling the chamber with the hydrogel via a tube (reads on applicant's claim amendments that are subject to the new matter objection above).

13. However, Eckenhoff et al does not a valve between the reservoir and the output needle. Ziaie et al teaches that it is known to have a valve (500; Fig 9-10) defining a chamber and interconnecting the reservoir and the output cannula (Fig 13), the valve movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle (Fig 9-10, 13; [0017, 0028, 0143-0147] and discussion of "Hydrogel-Activated Devices"); the valve including a hydrogel microscale valve having a flexible membrane (104) for dividing the valve chamber into a drug flow portion (110) and a trigger receiving portion (103) and a trigger (102) position within the trigger receiving portion of the valve chamber and having a first configuration with the valve in the non-actuated position and a second configuration with the valve in the actuated position (Fig 9) for the purpose of controlling drug delivery either in response to a pre-determined stimulus or for pulsatile delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the reservoir to output needle connection as taught by Eckenhoff et al with the hydrogel activated microvalve as taught by Ziaie et al for the purpose of controlling drug delivery either in response to a pre-determined stimulus or for pulsatile delivery.

Allowable Subject Matter

14. Claim 26 is allowed.

15. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

16. Applicant's arguments with respect to claims 21, 24, 26-28 have been considered but are moot in view of the new ground(s) of rejection.

17. The Examiner notes that the arguments recited in the Applicant's remarks focus solely on how the cited prior art references do not teach the applicant's current claim amendments. The claim amendments, however, are new matter additions. Lastly, the Examiner references the italicized portion of the Eckenhoff rejection as an example of the cited prior art teaching the applicant's claim amendments, regardless of the new matter rejections.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767